UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL
SAFETY AND POLLUTION
PREVENTION

August 23, 2013

MEMORANDUM

Subject: Efficacy Review for Pure Bright™ Germicidal Ultra Bleach, EPA Reg. No. 70271-13; DB Barcode D411896 and Tecumseh B™ EPA Reg. No. 70271-24; DB Barcode D411862

From: Ibrahim Laniyan, Ph.D.
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MDP 8/26/13

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Applicant: KIK International, Inc.
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Formulation from the Label: (70271-13)

Active Ingredient	% by wt.
Sodium Hypochlorite	6.0%
Other Ingredients:	94.0 %
Total	100.0 %

Formulation from the Label: (70271-24)

Active Ingredient	% by wt.
Sodium Hypochlorite	8.25%
Other Ingredients:	91.75 %
Total	100.0 %

I. BACKGROUND

The product, Pure Bright Germicidal Ultra Bleach (EPA Reg. No. 70271-13), is an EPA-approved disinfectant (bactericide, fungicide, virucide), sanitizer, mildewcide, and deodorizer for use on hard, non-porous surfaces in household, commercial, institutional, food service, animal care, and hospital or medical environments. In addition it has use as a laundry sanitizer. The applicant requested an amendment to the registration of this product to add 21 organisms to the label and to make some minor modifications to the label as outlined in the transmittal letter. The registrant requests that the 21 studies be bridged to Tecumseh B (EPA Reg. #: 70271-24). Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package identified as D411896 contained a letter from the applicant's representative to EPA (dated April 23, 2013), EPA Form 8570-1(Application for Pesticide), EPA Form 8570-34 (Certification with Respect to Citation of Data), EPA Form 8570-35 (Data Matrix), twenty one efficacy studies ((MRIDs 491096-01 to 491096-21) with a Statement of No Data Confidentiality Claims embedded in each MRID, and the proposed product label (dated 04/23/2013).

II. USE DIRECTIONS

The product is designed for disinfecting and sanitizing surfaces. The product may be used to treat hard, non-porous surfaces such as appliances, bathtubs, cages, counter tops, cutting boards (hard, non-porous plastic), faucets, floors, furniture, garbage disposals, kennels, mops, shower curtains, shower walls, showers, sinks, toys, trash bins, trash cans, walls, and work surfaces. The proposed label indicates that the product may be used on hard, non-porous surfaces including: glass, glazed ceramic tile, glazed porcelain, linoleum, painted woodwork, and vinyl. Directions on the proposed label provide the following information regarding preparation and use of the product:

As a disinfectant against *Clostridium difficile* spores: Clean surfaces by removing gross filth. Apply a 1:10 use solution of the product (~5000 ppm available chlorine) to surfaces. Let stand for 10 minutes. Rinse and air dry.

As a disinfectant against other label-specified microorganisms: Use ¾ cup of the product per 1 gallon of water (a 1:21 dilution). Wash, rinse, or wipe surfaces. Then, apply use solution. Let stand for 5 minutes. Rinse thoroughly and air dry.

As a laundry sanitizer: Add 1 1/4 cup of the product per laundry load for a conventional washing machine (16 gallon capacity). Add 2/3 cup of the product per laundry load for an automatic front loading washing machine (8 gallon capacity). Add to pre-soak, wash water. If clothes are in machine, dilute product with 1 quart of the wash water before adding.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments (Additional Bacteria): Effectiveness of disinfectants against specific bacteria other than those named in the AOAC Use-Dilution Method, AOAC Germicidal Spray Products as Disinfectants Method, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method, must be determined by either the

AOAC Use-Dilution Method or the AOAC Germicidal Spray Products as Disinfectants Method. Ten carriers must be tested against each specific microorganism with each of 2 product samples, representing 2 different product lots at the LCL. To support products labeled as "disinfectants" for specific bacteria (other than those bacteria named in the above test methods), killing of the specific microorganism on all carriers is required.

Sporicidal Disinfectant against *Clostridium difficile*: The Agency has established interim guidance for the efficacy evaluation of antimicrobial products (e.g., dilutable products, ready-to-use products, spray products, vapor, gases, and towelettes) that are labeled for use to treat hard, non-porous surfaces in healthcare settings contaminated with spores of *Clostridium difficile*. The effectiveness of such a product must be substantiated by data derived from one of the following two test methods: AOAC Method 2008.05: Quantitative Three Step Method (Efficacy of Liquid Sporicides Against Spores of *Bacillus subtilis* on a Hard Nonporous Surface); and ASTM E 2197-02: Standard Quantitative Carrier Test Method to Evaluate the Bactericidal, Fungicidal, Mycobactericidal, and Sporicidal Potencies of Liquid Chemical Germicides. Modifications to each test method will be necessary to specifically accommodate spores of *Clostridium difficile*. Because *Clostridium difficile* is an obligate anaerobe, testing should ensure adequate incubation conditions for the recovery of viable spores. Three product batches should be tested at or below the lower certified limit(s) (LCL) listed on the confidential statement of formula (CSF) of the product. The toxigenic strains, ATCC 43598, of *Clostridium difficile* must be used for testing. For towelette and spray formulations, the Agency will accept testing of the liquid expressed directly from towelettes or collected directly from spray containers using one of the quantitative methods and conditions specified above. All products should be tested with a 3-part soil load incorporated into the test inoculum by adding 25 µl of 5% bovine serum albumin, 35 µl of 5% yeast extract and 100 µl of 0.4% mucin to 340 µl of the spore suspension. Results must show a minimum 6 log reduction of viable spores in 10 minutes or less. For towelette products, wetness determination test will be used to generate the contact time. Control carrier counts must be greater than 10^6 spores/carrier. The titer and purity of the final spore preparation must be $>10^8$ spores/mL, and >95% spores. ASTM Standard E2839-11 specifies procedures for achieving the 95% purity. The acid resistance of purified spores should be assessed against 2.5 M hydrochloric acid (see ASTM Standard E2839-11). The spores are considered acid-resistant if a log reduction of 0-2 is exhibited following 10 minutes of exposure to 2.5 M HCl.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi, Using a Modified AOAC Use-Dilution Method): The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. The inoculum in the test must be modified to provide a concentration of at least 10^6 conidia per carrier. Ten carriers on each of 2 product samples representing 2 different product lots at the LCL must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Note: As an interim policy, EPA is accepting studies with dried carrier counts that are at least 10^4 for *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans*. EPA recognizes laboratories are experiencing problems in maintaining dried carrier counts at the 10^6 level. This interim policy will be in effect until EPA determines that the laboratories are able to achieve consistent carrier counts at the 10^6 level.

Virucides: The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-

Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots at the LCL of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces): The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots at the LCL against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Laundry Sanitizer: The effectiveness of laundry sanitizers must be supported by data that show that the product will substantially reduce the numbers of test bacteria on fabric and in laundry water. Laundry additives may either be used as soaking treatments prior to laundering or as treatments added during laundry operations. The label must specify the type of use. Laundry additives may be recommended for household/coin-operated machine use or commercial-industrial-institutional use. The label must specify the type of use. There is a significant difference in the water to fabric ratio between these two uses, which may affect the efficacy of the product. Tests should be conducted using a simulated-use procedure such as Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives" or a simulated use study involving washing machines. Tests should be performed with each of 3 product samples, representing 3 different lots, one of which is at least 60 days old. Tests should be conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Products labeled as being suitable for hospital use must also be tested against *Pseudomonas aeruginosa* (ATCC 15442). Each product lot must be tested with 3 fabrics swatches against each of the test organisms. The method employed must include subculturing of both the fabric and the laundry water. The laundry water to media volume ratio must not exceed 1:40. Testing of a 0.5 mL sample of laundry water from the simulated washing device (or a 5 mL sample from the automatic washer) is recommended. Results from a quantitative bacteriological assay must be reported. Results must show a bacterial reduction of 99.9% over the control count for both fabric and laundry water for each organism tested. The label directions for use of laundry additives should specify the machine cycle in which the product is to be added, as well as water level, temperature, and treatment time. Compatibility of the treatment with other laundry additives should be determined in testing and addressed in labeling, when applicable. These Agency standards are presented in DIS/TSS-13, and do not apply to sodium-calcium hypochlorites, sodium-potassium dichloro-s-triazinetriones, or trichloro-s-triazinetrione.

Note: The water to fabric ratio in industrial laundering operations is about 5:1. Dosages may be based on pounds of fabric for industrial machines. The water to fabric ratio in household laundering operations is 10:1 although in high efficiency laundry machines, this ratio can be as low as 2.5:1.

IV. BRIEF DESCRIPTION OF THE DATA

Note: The product lots 121920645M, 122291611M, 122350323M, 123492206M, 130220955M and 130250719M were all tested at 5.7% Sodium Hypochlorite.

1. MRID 491096-01 "Standard Test Method for the Evaluation of Laundry Sanitizers," Test Organism: Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592), for Pure Bright Germicidal Ultra Bleach, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – March 14, 2013. Project Number A14681.

This study was conducted against Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592). Two lots (Lot Nos. 130220955M and 130250719M) of the product, Pure Bright Germicidal Ultra Bleach, were tested using ATS Protocol No. KIK02012213.LSAN.2 (copy provided). The laboratory report referenced Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives." The test organism was transferred daily on Nutrient Agar A slants. At least 3 but less than 16 transfers were made. Slants were incubated for 23-25 hours at 35-37ºC. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. The test substance concentrate was diluted to 56,500-57,000 ppm sodium hypochlorite using sterile tap water and titrated for confirmation. Using this diluted test substance, an equivalent use dilution of the product was prepared by adding 3.00 mL of the product and 614.4 mL of sterilized tap water (1¼ cup +16 gallon dilution; ~1:205 dilution) for efficacy testing. The carriers for testing were prepared by boiling plain ~300 g cotton weave fabric (approximately 80 x 80 threads/inch) in a solution of ~1.50 grams of Na_2CO_3, ~1.50 grams of Triton X-100, and 3 liters of deionized water for 60 minutes. The fabric then was rinsed in boiling water for 5 minutes and then rinsed in cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in the water to help remove the wetting agent. After air-drying, the fabric was cut into 5 cm (~2 inch) wide strips weighing 15±1 grams. Each fabric strip was wrapped around a stainless steel spindle between 12 and 13 times. The fabric wrapped spindles were autoclave sterilized. Swatches (1 inch by 1.5 inch) were cut from the remaining fabric. The fabric wrapped spindles and swatches were steam sterilized, allowed to cool, and held at room temperature until use. Three swatches per product lot per test organism were inoculated with 30 µL of the prepared organism culture, and dried in an incubator for 10 minutes at 35-37°C. After drying, the swatches were each inserted between the 6^{th} and 7^{th} lap of a wrapped spindle. Each spindle contained three dried, contaminated swatches. The spindles were placed in the sterile bottles containing the use solution and subjected to a simulated tumble-wash at 45-60 RPM for 10 minutes at 20°C. Following the simulated wash, a 1.00 mL aliquot of the wash water was transferred to a vessel containing 9.0 mL of Letheen Broth with 1.0% sodium thiosulfate to neutralize. Each fabric swatch was transferred to 10 mL of Letheen Broth with 1.0% sodium thiosulfate to neutralize. The fabric swatches were then vortex mixed for at least 10 seconds to extract fabric-bound microorganisms. A 1.00 mL aliquot of the neutralizing subculture medium was transferred to 9 mL of sterile diluent; representing the 10^{-1} dilution. Ten-fold serial dilutions were continued through the 10^{-4} dilution. Each dilution was plated using 1.00 mL of the 10^{0} to 10^{-4} dilutions in duplicate on tryptic soy agar with 5% sheep's blood. All subcultures were

incubated for 46.25 hours at 35-37°C. Following incubation, standard plate count procedures were used to determine the average colony forming units per carrier (CFU/carrier) and per milliliter of wash water (CFU/mL). Controls included those for initial suspension count, carrier population count, purity, sterility, and neutralization confirmation.

Note: Antimicrobial susceptibility testing was performed by ATS Labs for Community Acquired Methicillin Resistant *Staphylococcus aureus* – CA-MRSA Genotype USA 300 (NARSA NRS 384) to verify the antibiotic resistance pattern stated. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using oxacillin antibiotic disks to test for methicillin resistance. *Staphylococcus aureus* (ATCC 25923) was the Methicillin Resistant Quality Control (QC) organism. The zone of inhibition in mm, was in the CLSI acceptable range for the test organism and the QC organism. Refer to page 20 and table 6 of the laboratory report. No protocol amendments or deviations were required for this study.

2. MRID 491096-02 "Standard Test Method for the Evaluation of Laundry Sanitizers," Test Organism: *Pseudomonas aeruginosa* (ATCC 15442), for Pure Bright Germicidal Ultra Bleach, by Jill Ruhme. Study conducted at ATS Labs. Study completion date – March 14, 2013. Project Number A14680.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442), Three lots [Lot Nos. 130220955M, 130250719M and 123492206M (≥60 days old) of the product, Pure Bright Germicidal Ultra Bleach, were tested using ATS Protocol No. KIK02012213.LSAN.1 (copy provided). The laboratory report referenced Petrocci and Clarke's "Proposed Test Method for Antimicrobial Laundry Additives." The test organism was transferred daily on Nutrient Agar A slants. At least 3 but less than 16 transfers were made. Slants were incubated for 23-25 hours at 35-37°C. Fetal bovine serum was added to each inoculum to achieve a 5% organic soil load. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent use dilution of the product was prepared by adding 3.00 mL of the product and 614.4 mL of sterilized tap water (1¼ cup +16 gallon dilution; ~1:205 dilution). The carriers for testing were prepared by boiling plain ~300 g cotton weave fabric (approximately 80 x 80 threads/inch) in a solution of ~1.50 grams of Na_2CO_3, ~1.50 grams of Triton X-100, and 3 liters of deionized water for 60 minutes. The fabric then was rinsed in boiling water for 5 minutes and then rinsed in cold water for a minimum of 5 minutes. During the rinsing procedure, the fabric was mixed in the water to help remove the wetting agent. After air-drying, the fabric was cut into 5 cm (~2 inch) wide strips weighing 15±1 grams. Each fabric strip was wrapped around a stainless steel spindle between 12 and 13 times. The fabric wrapped spindles were autoclave sterilized. Swatches (1 inch by 1.5 inch) were cut from the remaining fabric. The fabric wrapped spindles and swatches were steam sterilized, allowed to cool, and held at room temperature until use. Three swatches per product lot per test organism were inoculated with 30 µL of the prepared organism culture, and dried in an incubator for 10 minutes at 35-37°C. After drying, the swatches were each inserted between the 6^{th} and 7^{th} lap of a wrapped spindle. Each spindle contained three dried, contaminated swatches. The spindles were placed in the sterile bottles containing the use solution and subjected to a simulated tumble-wash at 45-60 RPM for 10 minutes at 20°C. Following the simulated wash, a 1.00 mL aliquot of the wash water was transferred to a vessel containing 9.0 mL of Letheen Broth with 0.1% sodium thiosulfate to neutralize. Each fabric swatch was transferred to 10 mL of Letheen Broth with 0.1% sodium thiosulfate to neutralize. The fabric swatches were then vortex mixed for at least 10 seconds to extract fabric-bound microorganisms. A 1.00 mL aliquot of the neutralizing subculture medium was transferred to 9 mL of sterile diluent; representing the 10^{-1} dilution. Ten-fold serial dilutions were continued through the 10^{-4} dilution. Each dilution was plated using 1.00 mL of the 10^{0} to 10^{-4} dilutions in duplicate on tryptic soy agar with 5% sheep's blood. All subcultures were

incubated for 46.25 hours at 35-37°C. Following incubation, standard plate count procedures were used to determine the average colony forming units per carrier (CFU/carrier) and per milliliter of wash water (CFU/mL). Controls included those for initial suspension count, carrier population count, purity, sterility, and neutralization confirmation.

3. MRID 491096-03 "AOAC Use-Dilution Method." Test Organism: *Streptococcus pneumoniae* (ATCC 6305) for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – March 18, 2013. Project Number A14658.

This study was conducted against *Streptococcus pneumoniae* (ATCC 6305). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.2 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 6.0 mL of test substance and 127.8 mL of sterile tap water. The prepared test substance was used within three hours of preparation. The stock culture of test organism on TSA +5% Sheep Blood (BAP) was inoculated to sterile Thioglycollate Broth to target $1x10^8$ CFU/ML. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 25-30°C at 62% relative humidity. For each lot of product, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of primary (1°) subculture medium, Brain Heart Infusion (BHI) Broth + 0.1% Sodium Thiosulfate, to neutralize. Beginning at about 25-60 minutes after primary subculture, the carriers were transferred to secondary (2°) subculture tubes containing 10 mL of BHI Broth for secondary neutralization. All subcultures were incubated for 48±2 hours at 35-37°C in CO_2. Subcultures were stored at 2-8°C for 2 days and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in this study were reviewed.

4. MRID 491096-04 "AOAC Use-Dilution Method." Test Organism: *Escherichia coli* - Carbapenem Resistant (CDC 81371) for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – April 2, 2013. Project Number A14783.

This study was conducted against *Escherichia coli* - Carbapenem Resistant - CPR (CDC 81371). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02031513.UD.1 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 12.0 mL of test substance and 255.96 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of Synthetic Broth culture medium and incubated for 24±2 hours at 35-37°C and was transferred daily until use. The final test culture was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled. The final test culture was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one

mL of culture and drying them for 39 minutes at 35-37°C at 40% relative humidity. Carriers were used in the test procedure within 2 hours of drying. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 21.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subcultures were incubated for 48±2 hours at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation and antibiotic resistance.

Note: Antibiotic resistance of *Escherichia coli* - Carbapenem Resistant - CPR (CDC 81371) was verified on a representative culture from the day of testing. The laboratory performed a Modified Hodge Test to confirm that the test organism produces a carbapenemase and is, therefore, carbapenem resistant. *Klebsiella pneumoniae* (ATCC BAA-1705) was the positive control organism. *Klebsiella pneumoniae* (ATCC BAA-1706) was the negative control organism. By inactivating the effect of meropenem and allowing growth of *Escherichia coli* (ATCC 25922), the presence of carbapenemase was demonstrated. Thus, antibiotic resistance of *Escherichia coli* - Carbapenem Resistant (CDC 81371) to carbapenem was confirmed. See page 10 and Table 5 of the laboratory report.

5. MRID 491096-05 "AOAC Use-Dilution Method." Test Organism: *Legionella pneumophila* (ATCC 33153), for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – March 13, 2013. Project Number A14660.

This study was conducted against *Legionella pneumophila* (ATCC 33153). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.4 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 16.0 mL of test substance and 341.28 mL of sterile tap water. The prepared test substance was used within three hours of preparation. The stock culture of test organism was inoculated to a sufficient number of Buffered Charcoal Yeast Extract (BCYE) agar plates which were incubated for 4 days at 35-37°C. The organism was then transferred to Butterfield's Buffer to yield a 4.0 Mcfarland turbidity standard and mixed thoroughly prior to use. No organic soil load was required. The culture was transferred to the Penicylinders which were immersed for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and then dried for 39 minutes at 25-30°C at 65% relative humidity. For each lot of product (per subculture), 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of primary (1°) subculture medium, BCYE Medium + 0.1% Sodium Thiosulfate, to neutralize. Beginning at about 25-60 minutes after primary subculture, the carriers were transferred to secondary (2°) subculture tubes containing 10 mL of BCYE Medium for secondary neutralization. All subcultures were incubated for 3 days at 35-37°C in CO_2, then were examined for the presence or absence of growth. Due to the dark pigment of the BCYE broth, the broth tubes were sub cultured to BCYE agar before incubation. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

6. MRID 491096-06 "AOAC Use-Dilution Method," Test Organism: *Enterobacter cloacae* NDM-1 positive (CDC 1000654) for product Pure Bright Germicidal Ultra

Bleach, by Jill Ruhme, B.S. Study conducted at ATS Labs. Study completion date - March 5, 2013. Project Number A14666.

This study was conducted against *Enterobacter cloacae* NDM-1 positive (CDC 1000654). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.10 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of Tryptic Soy Broth growth medium and incubated for 24±2 hours at 25-30°C and was transferred daily until use, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled and was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 35-37°C at 40% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subculture vessels and control plates were incubated for 48±2 hours at 25-30°C in CO_2. Following incubation, subcultures were stored at 2-8°C for 1 day and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation and antibiotic resistance.

Note: Antibiotic sensitivity testing was performed using a representative culture from the day of testing to verify the stated antibiotic resistance pattern. This testing was performed at the University of Minnesota Physicians Outreach Laboratory. See page 18, Attachment I of the laboratory report for the Antibiotic Sensitivity Testing Results.

Note: Protocol deviations/amendments reported in this study were reviewed.

7. MRID 491096-07 "AOAC Use-Dilution Method." Test Organism: *Campylobacter jejuni* (ATCC 29428), for product Pure Bright Germicidal Ultra Bleach, by Jill Ruhme, B.S. Study conducted at ATS Labs. Study completion date - March 7, 2013. Project Number A14668.

This study was conducted against *Campylobacter jejuni* (ATCC 29428). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.12 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. From frozen stock, the test organism was inoculated to Tryptic Soy Agar + 5% Sheep Blood agar plates (BAP) and incubated for 2-5 days at 35-37°C under microaerophilic conditions in a CampyPak™ Plus. From there, multiple BAP were inoculated and incubated for 5 days at 35-37°C in a CampyPak™ Plus. Finally a bacterial suspension was inoculated to sterile Thioglycollate Broth to target 1.0×10^8 CFU/mL and mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one

mL of culture and drying them for 38 minutes at 25-30°C at 65% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium) and gently shaken. The entire volume of the subculture broths were individually transferred to the surface of a filter membrane (0.2 µm porosity) pre-wetted with 10.0 mL of neutralizing subculture medium and filtered using a vacuum pump. Each filter membrane was washed with ≥50 mL of sterile saline and then was removed aseptically from the filter unit and placed on the surface of a BAP plate and incubated for 5 days at 35-37°C in a CampyPak™ Plus. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

8. MRID 491096-08 "AOAC Use-Dilution Method." Test Organism: *Listeria monocytogenes* (ATCC 19117), for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – March 5, 2013. Project Number A14661.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.5 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 16.0 mL of test substance and 341.28 mL of sterile tap water. The prepared test substance was used within three hours of preparation. Brain Heart Infusion (BHI) broth cultures of the test organisms were prepared by inoculation of an initial tube of BHI broth from a stock slant and performing four daily subculture transfers. The final subculture was incubated for 48-54 hours at 35-37ºC, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled and thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 39 minutes at 25-30°C at 65% relative humidity. For each lot of product, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 19.0°C and then were transferred by wire hook at staggered intervals to 10 mL of primary (1°) subculture medium, Brain Heart Infusion (BHI) Broth + 0.1% Sodium Thiosulfate, to neutralize. Beginning at about 25-60 minutes after primary subculture, the carriers were transferred to secondary (2°) subculture tubes containing 10 mL of BHI Broth for secondary neutralization. All subcultures were incubated for 48±2 hours at 35-37°C in CO_2. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

9. MRID 491096-09 "AOAC Use-Dilution Method." Test Organism: *Enterococcus faecalis* (ATCC 29212) for product Pure Bright Germicidal Ultra Bleach, by Joshua Leudtke, M.S. Study conducted at ATS Labs. Study completion date - March 5, 2013. Project Number A14657.

This study was conducted against *Enterococcus faecalis* (ATCC 29212). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.1 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾

cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of sterile Thioglycollate Broth growth medium and incubated for 24±2 hours at 35-37°C and was transferred daily until use, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled and was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 40 minutes at 25-30°C at 65% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C in CO_2. Following incubation, subcultures were stored at 2-8°C for 1 day and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in this study were reviewed.

10. MRID 491096-10 "AOAC Use-Dilution Method." Test Organism: *Escherichia coli* NDM-1 positive (CDC 1001728) for product Pure Bright Germicidal Ultra Bleach, by Jill Ruhme, B.S. Study conducted at ATS Labs. Study completion date - March 4, 2013. Project Number A14667.

This study was conducted against *Escherichia coli* NDM-1 positive (CDC 1001728). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.11 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of Nutrient Broth growth medium and incubated for 24±2 hours at 25-30°C and was transferred daily until use. The final test culture was incubated for 48-54 hours at 35-37°C, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled and was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 35-37°C at 40% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 21.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°. Following incubation, subcultures were stored at 2-8°C for 2 days and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, neutralization confirmation and antibiotic resistance.

Note: Antibiotic sensitivity testing was performed using a representative culture from the day of testing to verify the stated antibiotic resistance pattern. This testing was performed at the

University of Minnesota Physicians Outreach Laboratory. See page 18, Attachment I of the laboratory report for the Antibiotic Sensitivity Testing Results.

11. MRID 491096-11 "AOAC Use-Dilution Method." Test Organism: *Klebsiella pneumonia* - NDM-1 positive (CDC 1000527) for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date - March 5, 2013. Project Number A14665.

This study was conducted against *Klebsiella pneumonia* - NDM-1 positive (CDC 1000527). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.9 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of Nutrient Broth growth medium and incubated for 24±2 hours at 35-37°C and was transferred daily until use. The final test culture was incubated for 48-54 hours at 35-37°C, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled and was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 35-37°C at 40% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 21.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°. Following incubation, subcultures were stored at 2-8°C for 2 days and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antibiotic sensitivity testing was performed using a representative culture from the day of testing to verify the stated antibiotic resistance pattern. This testing was performed at the University of Minnesota Physicians Outreach Laboratory. See page 18, Attachment I of the laboratory report for the Antibiotic Sensitivity Testing Results.

12. MRID 491096-12 "AOAC Use-Dilution Method." Test Organism: Extended-Spectrum Beta-lactamase (ESBL) *Escherichia coli* (*ATCC BAA-196*) for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – Feb. 28, 2013. Project Number A14663.

This study was conducted against Extended-Spectrum Beta-lactamase (ESBL) *Escherichia coli* (*ATCC BAA-196*). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.7 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of Nutrient Broth culture medium and incubated for 24±2 hours at 35-37°C and was transferred daily until use. The final test culture was incubated for 48-54 hours at 35-37°C, then was vortexed for 3 to 4 seconds and

allowed to stand for ≥10 minutes. The upper portion was removed and the sediment was pooled. The final test culture was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 35-37°C at 41% relative humidity. Carriers were used in the test procedure within 2 hours of drying. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subcultures were incubated for 48±2 hours at 35-37°C in CO2. Following incubation, subcultures were stored at 2-8°C for 2 days and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antibiotic susceptibility testing of Extended Spectrum Beta-lactamase (ESBL) *Escherichia coli* (*ATCC BAA-196*) was performed by ATS Labs to verify the antimicrobial resistance pattern of an ESBL. The Etest® assay was performed on a representative culture from the day of testing to confirm that the test organism is an ESBL producer. *Klebsiella pneumoniae* (ATCC 700603) was the positive control organism (ESBL positive) and *Escherichia coli* (ATCC 35218) was the negative control organism (ESBL negative). See page 17 and Table 5 of the laboratory report.

13. MRID 491096-13 "AOAC Use-Dilution Method." Test Organism: Community Acquired Methicillin Resistant *Staphylococcus aureus* – CA-MRSA Genotype USA 300 (NARSA NRS 384), for product Pure Bright Germicidal Ultra Bleach, by Joshua Luedtke, M.S. Study conducted at ATS Labs. Study completion date – Feb. 28, 2013. Project Number A14662.

This study was conducted against Community Acquired Methicillin Resistant *Staphylococcus aureus* – CA-MRSA Genotype USA 300 (NARSA NRS 384). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.6 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10mL tube of Synthetic Broth growth medium and incubated for 24±2 hours at 35-37°C and was transferred daily until use. The final test culture was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. The upper portion was removed and the sediment was pooled and thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 39 minutes at 35-37°C at 40% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subcultures were incubated for 48±2 hours at 35-37°C. Following incubation, subcultures were stored at 2-8°C for 2 days and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Antimicrobial susceptibility testing was performed by ATS Labs for Community Acquired Methicillin Resistant *Staphylococcus aureus* – CA-MRSA Genotype USA 300 (NARSA NRS 384) to verify the antibiotic resistance pattern stated. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using oxacillin antibiotic disks to test for methicillin resistance. *Staphylococcus aureus* (ATCC 25923) was the Methicillin Resistant Quality Control (QC) organism. The zone of inhibition in mm, was in the CLSI acceptable range for the test organism and the QC organism. Refer to page 18 and table 6 of the laboratory report.

14. MRID 491096-14 "AOAC Use-Dilution Method," Test Organism: *Acinetobacter baumannii* (ATCC 19606) for product Pure Bright Germicidal Ultra Bleach, by Joshua Leudtke, M.S. Study conducted at ATS Labs. Study completion date – Feb. 28, 2013. Project Number A14659.

This study was conducted against *Acinetobacter baumannii* (ATCC 19606). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.3 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10 mL tube of Tryptic Soy Broth growth medium and incubated for 24±2 hours at 25-30°C and was transferred daily until use, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. The upper portion was removed and the sediment was pooled and was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 35-37°C at 41% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, subcultures were stored at 2-8°C for 2 days and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

15. MRID 491096-15 "AOAC Use-Dilution Method." Test Organism: Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) for product Pure Bright Germicidal Ultra Bleach, by Joshua Leudtke, M.S. Study conducted at ATS Labs. Study completion date - March 4, 2013. Project Number A14664.

This study was conducted against Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575). Two lots of test substance (130220955M and 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.UD.8 (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 35.0 mL of test substance and 745.5 mL of sterile tap water. The prepared test substance was used within three hours of preparation. A 10 µL aliquot of stock culture was inoculated to a 10mL tube of Thioglycollate Broth growth medium and incubated for 24±2 hours at 35-37°C and was transferred daily until use, then was vortexed for 3 to 4 seconds and allowed to stand for ≥10 minutes prior to use. The upper portion was removed

and the sediment was pooled and was thoroughly mixed prior to use. No organic soil load was required. The test culture was transferred to Penicylinders by immersing them for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and drying them for 38 minutes at 25-30°C at 65% relative humidity. For each lot of test substance, 10 contaminated and dried carriers were placed into separate tubes containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 20.0°C and then were transferred by wire hook at staggered intervals to 10 mL of Letheen Broth with 0.1% sodium thiosulfate (neutralizing subculture medium). All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C in CO2. Following incubation, subcultures were stored at 2-8°C for 1 day and then were examined for the presence or absence of visible growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol deviations/amendments reported in this study were reviewed.

Note: Antimicrobial susceptibility testing was performed by ATS Labs for Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575) to verify the antibiotic resistance pattern stated. The Kirby Bauer susceptibility assay was performed utilizing a representative culture from the day of testing and using vancomycin antibiotic disks to test for resistance. *Staphylococcus aureus* (ATCC 25923) was the Quality Control (QC) organism. The zone of inhibition in mm, was in the CLSI acceptable range for the test organism and the QC organism. Refer to page 18 and table 6 for results.

16. MRID 491096-16 "Standard Quantitative Disk Carrier Test Method." Test Organism: *Clostridium difficile* – spore form (ATCC 43598), for product Pure Bright Germicidal Ultra Bleach, by Nicole Albert, B.S. Study conducted at ATS Labs. Study completion date – Sept. 28, 2012. Project Number A14011.

This study was conducted against *Clostridium difficile* – spore form (ATCC 43598), using three lots of test substance. Lot 121920645M (≥60 days old), lot 122291611M and lot 122350323M were tested using ATS Laboratory Protocol No. KIK02081612.QDCT (copy provided), prepared for KIK Custom Products. The product Lot 121920645M was at least 60 days old at the time of testing. On the day of testing, each lot of test substance concentrate was adjusted to 4800-5000 ppm available chorine in autoclave-sterilized tap water per ATS Labs SOP CGT- 0090. Lot 121920645M dilution, 10.0 mL of test substance plus 98.0 mL diluent, lot 122291611M dilution, 10.0 mL test substance plus 109.0 mL diluent and lot 122350323M dilution, 10.0 mL plus 107.0 mL diluent. The prepared test substance was used within three hours of preparation. Stock test organism inoculated to 80 CDC Anaerobic Blood agar plates and incubated for 9 days at 35-37ºC under anaerobic conditions was removed from each plate to a 50 mL conical tube and washed three times in sterile deionized water and was stored at 2-8°C for 2 months prior to use. Brushed stainless steel carriers were used in the test. Up to 20 sterile carriers were transferred to individual sterile Petri dishes matted with filter paper. Ten (10.0) µL of culture was placed in the center of each disk. After all disks in each petri dish were inoculated, the dishes were covered and the contaminated carriers were placed in a desiccator containing active desiccant. A vacuum was drawn and the carriers were dried for ≥2 hours under ambient conditions. Only carriers not showing signs of run-off were used in the tests. The contaminated and dried carriers were placed into separate sterile 15 mL flat-bottomed Teflon QCT vials with the contaminated side facing up. Fifty (50) µL of test substance at its use dilution was applied to the center of each disk. The test substance was allowed to remain in contact with the disk for 10 minutes at room temperature (21°C) and 39% relative humidity. Following the 10-min exposures, 10.0 mL of neutralizer (Letheen Broth + 0.1% of sodium thiosulfate) was added to each vial containing the carriers. The corresponding HCl control consisted of a modified fluid

thioglycollate medium. The surface of the carriers was scraped, the vials containing the carriers were vortex-mixed and the contents transferred to separate filter membranes with 0.2 or 0.45 µm porosity. The vials were rinsed and vortex-mixed four separate times and each time the rinse solutions were transferred to the same filter membranes. The contents were evacuated, after which each filter membrane was removed aseptically from the filter unit and placed on the surface of an agar plate (CCFA-HT Agar) for recovery of *C. difficile* spores. The subcultures were incubated anaerobically for 48±4 hours at 35-37°C prior to spore enumeration. Controls included those for culture purity, carrier sterility, neutralizer sterility, initial suspension population, neutralization confirmation, carrier population, and HCl resistance. All data measurements for these controls were within acceptance criteria.

17. MRID 491096-17 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Feline Calicivirus as a Surrogate Virus for Norovirus," for product Pure Bright Germicidal Ultra Bleach, by Mary Miller M.T. Study conducted at ATS Labs. Study completion date – Sept. 24, 2012. Project Number A13990.

This study was conducted against F-9 strain of Feline Calicivirus (ATCC VR-782). Two lots of test substance Pure Bright Germicidal Ultra Bleach (lot 122291611M and lot 122350323M) were tested using ATS Laboratory Protocol No. KIK02081612.FCAL (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 5.65% - 5.71% sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 1.00 mL of test substance and 21.30 mL of sterile tap water. The prepared test substance was used on the day of preparation. The host cell line was Crandel Reese Feline Kidney (CRFK) cells (ATCC CLL-94) seeded into multiwell cell cultures plates and maintained at 36-38°C in 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 5% (v/v) heat activated fetal bovine serum and 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. On the day of testing, one aliquot of stock virus was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of six 100 x 15 mm sterile glass petri dishes and air-drying at 20.0°C for 20 minutes at 50% relative humidity. For each batch of test substance assayed, two dried virus films were individually exposed to 2.00 mL of the use dilution of the test substance and held covered for 5 minutes at room temperature (21.0°C). Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The CRFK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

18. MRID 491096-18 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Human Coronavirus, for product Pure Bright Germicidal Ultra Bleach, by Shanen Conway, B.S. Study conducted at ATS Labs. Study completion date – March 14, 2013. Project Number A14635.

This study was conducted against Human Coronavirus (ATCC VR-740). Two lots of test substance Pure Bright Germicidal Ultra Bleach (lot 130220955M and lot 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.COR (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 2.0 mL of test substance and 42.6 mL of sterile tap water. The prepared test substance was used on the day of preparation. The host cell line was WI-38 (human lung) cells (ATCC CLL-75) seeded into multiwell cell cultures plates and maintained at 36-38°C in 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 2% (v/v) heat activated fetal bovine serum and 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. On the day of testing, one aliquot of stock virus was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of three 100 x 15 mm sterile glass petri dishes and air-drying at 20.0°C for 20 minutes at 50% relative humidity. For each lot of test substance assayed, one dried virus film was individually exposed to 2.00 mL of the use dilution of the test substance and held covered for 5 minutes at room temperature (20.0°C). Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The WI-38 cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 31-35°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 9 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: Protocol deviations/amendments reported in this study were reviewed.

19. MRID 491096-19 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Parainfluenza virus type 3, for product Pure Bright Germicidal Ultra Bleach, by Shanen Conway, B.S. Study conducted at ATS Labs. Study completion date – March 12, 2013. Project Number A14637.

This study was conducted against Parainfluenza virus type 3, ATCC VR-93, Strain C243. Two lots of test substance Pure Bright Germicidal Ultra Bleach (lot 130220955M and lot 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.PFLU (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 2.0 mL of test substance and 42.6 mL of sterile tap water. The prepared test substance was used on the day of preparation. The host cell line was bovine kidney (MDBK) cells (ATCC CLL-22) seeded into multiwell cell cultures plates and maintained at 36-38°C in 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 1% (v/v) heat activated fetal bovine serum and 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. On the day of testing, one aliquot of stock virus was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of three 100 x 15 mm sterile glass Petri dishes and air-drying at 20.0°C for 20 minutes at 40% relative humidity.

For each lot of test substance assayed, one dried virus film was individually exposed to 2.00 mL of the use dilution of the test substance and held covered for 5 minutes at room temperature (20.0°C). Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The MDBK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: Protocol deviations/amendments reported in this study were reviewed.

20. MRID 491096-20 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Virus: Influenza B virus, for product Pure Bright Germicidal Ultra Bleach, by Shanen Conway, B.S. Study conducted at ATS Labs. Study completion date – March 12, 2013. Project Number A14636.

This study was conducted against Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72. Two lots of test substance Pure Bright Germicidal Ultra Bleach (lot 130220955M and lot 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.FLUB (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 2.0 mL of test substance and 42.6 mL of sterile tap water. The prepared test substance was used on the day of preparation. The host cell line was Rhesus Monkey Kidney (RMK) cells, obtained from Diagnostic Hybrids. Cultures were maintained and used at 36-38°C in a humidified atmosphere of 5-7% CO_2. Test medium used to maintain the cell cultures was Minimum Essential Medium (MEM) supplemented with 1% (v/v) heat activated fetal bovine serum and 10 µg/mL gentamicin, 100 units/mL penicillin and 2.5 µg/mL amphotericin B. On the day of testing, one aliquot of stock virus was thawed and maintained at refrigerated temperature until used in the assay. The stock virus culture was adjusted to contain 1% fetal bovine serum as the organic soil load. Films of virus were prepared at staggered intervals by spreading 200 µL of virus uniformly over the bottoms of three 100 x 15 mm sterile glass Petri dishes and air-drying at 20.0°C for 20 minutes at 40% relative humidity. For each lot of test substance assayed, one dried virus film was individually exposed to 2.00 mL of the use dilution of the test substance and held covered for 5 minutes at room temperature (20.0°C). Near the end of the exposure time, the dried films were scraped with a cell scraper and at the end of the exposure time the virus-test substance mixtures were immediately passed through prepared individual Sephadex columns utilizing the syringe plungers to detoxify the mixtures. The filtrates (10^{-1} dilution) were then titered by 10-fold serial dilution and were assayed for infectivity. The RMK cells in multiwell culture dishes were inoculated in quadruplicate with 100 µL of the dilutions from the test and control groups and were incubated at 36-38°C in a humidified atmosphere of 5-7% CO_2. The cultures were scored periodically for 7 days for the absence or presence of CPE, cytotoxicity, and for viability. Controls included those for dried virus film recovery, cytotoxicity, neutralization and cell viability.

Note: Protocol deviations/amendments reported in this study were reviewed.

21. MRID 491096-21 "Fungicidal Use-Dilution Method." Test Organism: *Candida albicans* (ATCC 10231), for product Pure Bright Germicidal Ultra Bleach, by Jill

Ruhme, B.S. Study conducted at ATS Labs. Study completion date – March 14, 2013. Project Number A14679.

This study was conducted against *Candida albicans* (ATCC 10231). Two lots of test substance, Pure Bright Germicidal Ultra Bleach (Lot 130220955M and Lot 130250719M) were tested using ATS Laboratory Protocol No. KIK02012213.FUD (copy provided), prepared for KIK Custom Products. Using test substance concentrate adjusted to 56,500-57,000 ppm sodium hypochlorite, an equivalent dilution of ¾ cup per gallon (defined as ¾ cup of test substance plus 1 gallon of diluent) was prepared using 16.0 mL of test substance and 341.28 mL of sterile tap water. The prepared test substance was used within three hours of preparation. The stock culture of test organism was inoculated to a sufficient number of Sabouraud Dextrose agar plates which were incubated for 3 days at 25-30°C. The organism was then suspended in Butterfield's Buffer to yield a 4.0 Mcfarland turbidity standard and mixed thoroughly prior to use. No organic soil load was required. The culture was transferred to the Penicylinders which were immersed for 15±2 minutes in the prepared suspension at a ratio of one carrier per one mL of culture and then dried for 38 minutes at 35-37°C at 51% relative humidity. Each contaminated and dried carrier was placed into a separate tube containing 10.0 mL of the test substance at its use dilution. The carriers were exposed for 5 minutes at 21.0°C and then were transferred by wire hook at staggered intervals to 10 mL of primary (1°) neutralizing subculture medium, Sabouraud Dextrose broth + 0.1% Sodium Thiosulfate. Beginning at about 25-60 minutes after primary subculture, the carriers were transferred to secondary (2°) subculture tubes containing 10 mL of Sabouraud Dextrose broth + 0.07% Lecithin + 0.5% Tween 80 for secondary neutralization. All subcultures were incubated for 10 days at 25-30°C in CO_2 (see Protocol deviation). The subcultures were then examined visually for the presence or absence of growth. Controls included those for carrier population, purity, sterility, viability, and neutralization confirmation.

Note: Protocol Deviation: The protocol states all subcultures will be incubated for 2-3 days. The subcultures were inadvertently incubated for 10 days resulting in a protocol deviation. Since all test controls were valid and there was no growth in the subculture tubes, this deviation did not impact the outcome of the study.

V. RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested		Carrier Population (Log_{10}CFU/ Carrier)
		Lot # 130220955M	Lot # 130250719M	
5 - minute contact time – ¾ cup product with 1 gallon diluent (2500 ppm available chlorine)				
491096-03	*Streptococcus pneumoniae* (ATCC 6305)	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	4.37
491096-04	*Escherichia coli* – CPR (CDC 81371)	0/10	0/10	6.11
491096-05	*Legionella pneumophila* (ATCC 33153)	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	6.66

491096-06	*Enterobacter cloacae* NDM-1 positive (CDC 1000654)	0/10	0/10	7.18
491096-07	*Campylobacter jejuni* (ATCC 29428)	0/10	0/10	5.25
491096-08	*Listeria monocytogenes* (ATCC 19117)	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	5.25
491096-09	*Enterococcus faecalis* (ATCC 29212)	0/10	0/10	6.33
491096-10	*Escherichia coli* NDM-1 positive (CDC 1001728)	0/10	0/10	7.07
491096-11	*Klebsiella pneumonia* NDM-1 positive (CDC 1000527)	0/10	0/10	6.62
491096-12	ESBL *Escherichia coli* (*ATCC BAA-196*)	0/10	0/10	7.03
491096-13	CA-MRSA Genotype USA 300 (NARSA NRS 384)	0/10	0/10	7.07
491096-14	*Acinetobacter baumannii* (ATCC 19606)	0/10	0/10	6.75

MRID Number	**Organism**	**No. Exhibiting Growth/ Total No. Tested**		**Carrier Population (Log_{10}CFU/ Carrier)**
		Lot # 130220955M	**Lot # 130250719M**	
5 - minute contact time – ¾ cup product with 1 gallon diluent (2500 ppm available chlorine)				
491096-15	Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575)	0/10	0/10	6.72
491096-21	*Candida albicans* (ATCC 10231)	1° = 0/10 2° = 0/10	1° = 0/10 2° = 0/10	6.85

MRID Number	**Organism**	**Lot No.**	**Average No. Surviving**	**Microbes Initially Present**	**Percent Reduction**
			CFU/Carrier		
10 - Minute Contact Time – 1¼ cup product with 16 gallons diluent (1:205)					
491096-01	Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)	130220955M 130250719M	$<1 \times 10^1$ $<1 \times 10^1$	9.77×10^7 9.77×10^7	>99.9 >99.9
491096-02	*Pseudomonas aeruginosa* (ATCC 15442)	130220955M 130250719M 123492206M	$<1 \times 10^1$ $<1 \times 10^1$ $<1 \times 10^1$	1.41×10^6 1.41×10^6 1.41×10^6	>99.9 >99.9 >99.9

*≥60 Days old

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			CFU/Carrier		
10 - Minute Contact Time – 4800-5000 ppm available chorine					
491096-16	*Clostridium difficile* – spore form (ATCC 43598))	121920645M* 122291611M 122350323M	$<1.91 \times 10^0$ $<1.23 \times 10^0$ $<1.00 \times 10^0$	8.51×10^6 8.51×10^6 8.51×10^6	>99.9999 >99.9999 >99.9999

MRID Number	Organism	Results @ 5 Minute Contact Time ¾ cup product with 1 gallon diluent (2500 ppm available chlorine)			Dried Virus Count
			Lot # 122291611M	Lot # 122350323M	
491096-17	Feline Calcivirus F-9 strain (ATCC VR-782)	10^{-1} to 10^{-4} dilutions	Complete inactivation	Complete inactivation	$10^{5.50}$ $10^{5.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.50*}$	$\leq 10^{0.50}$	
			Lot # 130220955M	**Lot #** 130250719M	
491096-18	Human Coronavirus (ATCC VR-740)	10^{-1} to 10^{-7} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
491096-19	Parainfluenza virus type 3 Strain C243 (ATCC VR-93)	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.75}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	
491096-20	Influenza B virus Strain B/Hong Kong/5/72 (ATCC VR-823)	10^{-1} to 10^{-6} dilutions	Complete inactivation	Complete inactivation	$10^{4.50}$ $TCID_{50}$/0.1 mL
		$TCID_{50}$/0.1 mL	$\leq 10^{0.5}$	$\leq 10^{0.5}$	

VI. CONCLUSION

1.) The submitted efficacy data **support** the use of PURE BRIGHT™ GERMICIDAL ULTRA BLEACH and TECUMSEH B at an equivalent dilution of **3/4 cup product to 1 gallon** of sterile tap water (**minimum of 2500 ppm available chlorine**) as a disinfectant against the following organisms on **pre-cleaned** hard, non-porous surfaces for a **5-minute** contact time (no organic load was added):

Streptococcus pneumoniae (ATCC 6305)	MRID 491096-03
Escherichia coli – CPR (CDC 81371)	MRID 491096-04
Legionella pneumophila (ATCC 33153)	MRID 491096-05
Enterobacter cloacae NDM-1 positive (CDC 1000654)	MRID 491096-06

Campylobacter jejuni (ATCC 29428)	MRID 491096-07
Listeria monocytogenes (ATCC 19117)	MRID 491096-08
Enterococcus faecalis (ATCC 29212)	MRID 491096-09
Escherichia coli NDM-1 positive (CDC 1001728)	MRID 491096-10
Klebsiella pneumonia NDM-1 positive (CDC 1000527)	MRID 491096-11
ESBL *Escherichia coli* (*ATCC BAA-196*)	MRID 491096-12
CA-MRSA Genotype USA 300 (NARSA NRS 384)	MRID 491096-13
Acinetobacter baumannii (ATCC 19606)	MRID 491096-14
Vancomycin Resistant *Enterococcus faecalis* (ATCC 51575)	MRID 491096-15
Candida albicans (ATCC 10231)	MRID 491096-21

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Antibiotic resistance was demonstrated for resistant test organisms in confirmation tests. Neutralization confirmation testing showed positive growth of the microorganisms.

2.) The submitted efficacy data **support** the use of PURE BRIGHT™ GERMICIDAL ULTRA BLEACH and TECUMSEH B at an equivalent dilution of 1 ¼ cup product to 16 gallons of sterile tap water (~1:205 dilution) as a laundry sanitizer against the following bacteria in the presence of 5% organic soil load for a 10-minute contact time:

Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)	MRID 491096-01
Pseudomonas aeruginosa (ATCC 15442)	MRID 491096-02

Acceptable killing was observed in the subcultures of the required number of carriers tested against the required number of product lots. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth. Neutralization confirmation testing showed positive growth of the microorganisms. Antibiotic resistance was demonstrated for MRSA in confirmation tests.

3.) The submitted efficacy data **support** the use of PURE BRIGHT™ GERMICIDAL ULTRA BLEACH and TECUMSEH B at an equivalent dilution of ¾ cup of product with 1 gallon of sterile tap water (**minimum of 2500 ppm available chlorine**) with virucidal activity against the following microorganisms on hard, non-porous surfaces for a 5-minute contact time:

Feline Calcivirus (ATCC VR-782)	MRID 491096-17
Human Coronavirus (ATCC VR-740)	MRID 491096-18
Parainfluenza virus type 3, Strain C243 (ATCC VR-93)	MRID 491096-19
Influenza B virus, Strain B/Hong Kong/5/72 (ATCC VR-823)	MRID 491096-20

Recoverable virus titers of at least 10^4 were achieved. No cytotoxicity was observed. Complete inactivation (no growth) was indicated in all dilutions tested.

4.) The submitted data (MRID 491096-16) support the use of PURE BRIGHT™ GERMICIDAL ULTRA BLEACH and TECUMSEH B as a disinfectant with sporicidal activity against *Clostridium difficile* **on pre-cleaned** hard, non-porous surfaces for a contact tine of 10 minutes in a solution containing **5000 ppm available chlorine**. Controls which included those for culture purity, carrier sterility, neutralizer sterility, initial suspension population, neutralization confirmation, carrier population, and HCl resistance all gave acceptable results.

VI. LABEL

1. The label claims that Tecumseh B is an effective disinfectant against the following organisms on pre-cleaned hard, non-porous surfaces for a 5-minute contact time at a dilution of 2/3 cup of the product per 1 gallon (1/2 cup of bleach to ¾ gallon) of water (5000 ppm available chlorine):

Streptococcus pneumoniae (ATCC 6305)
Escherichia coli – CPR (CDC 81371)
Legionella pneumophila (ATCC 33153)
Enterobacter cloacae NDM-1 positive (CDC 1000654)
Campylobacter jejuni (ATCC 29428)
Listeria monocytogenes (ATCC 19117)
Enterococcus faecalis (ATCC 29212)
Escherichia coli NDM-1 positive (CDC 1001728)
Klebsiella pneumonia NDM-1 positive (CDC 1000527)
ESBL *Escherichia coli (ATCC BAA-196)*
CA-MRSA Genotype USA 300 (NARSA NRS 384)
Acinetobacter baumannii (ATCC 19606)
Vancomycin Resistant Enterococcus faecalis (ATCC 51575)
Candida albicans (ATCC 10231)
Feline Calcivirus (ATCC VR-782)
Human Coronavirus (ATCC VR-740)
Parainfluenza virus type 3, ATCC VR-93, Strain C243
Influenza B virus, ATCC VR-823, Strain B/Hong Kong/5/72

These claims are acceptable as they are supported by the submitted data.

2. The label claims that Tecumseh B is an effective laundry sanitizer against the following organisms at a dilution of 1 cups of product per 16 gallons of water:

Methicillin Resistant *Staphylococcus aureus* – MRSA (ATCC 33592)
Pseudomonas aeruginosa (ATCC 15442)

These claims are acceptable providing a contact time ≥ 10 minutes is added to the label.

3. The label claims that Tecumseh B is effective against *Clostridium difficile* on pre-cleaned hard, non-porous surfaces for a contact time of 10 minutes in 1 part product with 12 parts water (~5000 ppm available chlorine).

This claim is acceptable as it is supported by the submitted data.

4. Recommendations

- A contact time of ≥ 10 minutes needs to be added to the laundry sanitizing section on page 11.
- The dilution table on page 23 should include the laundry sanitizing recommendations (1 cup per 16 gallons).